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REMARKS

Claims 32, 33, 36-40, 42, 43, 46 and 47 are pending in the subject application. By this Amendment, applicants have amended claims 32, 33, 36-40 and 46. Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claims 32, 33, 40 and 46 can be found in the specification at, *inter alia*, page 6, lines 2-17. Claims 36 and 37 have been amended to introduce certain formatting changes, and claims 38 and 39 have been amended merely to correct a grammatical error. Accordingly, applicants respectfully request entry of this Amendment. After entry of this Amendment, claims 32, 33, 36-40, 42, 43, 46 and 47 will be pending and under examination.

Claim Rejections under 35 U.S.C. §103(a)

In the January 11, 2005 Final Office Action, and as repeated in the July 13, 2005 Advisory Action, the Examiner rejected claims 32, 33, 36-40, 42, 43, 46 and 47 under 35 U.S.C. §103(a) as allegedly unpatentable over Wilson et al. (Patent No. 4,816,563) and Ablashi et al. (*Biotherapy*, 1996, Vol. 9, pp. 81-86). The Examiner stated that Ablashi et al. teach a method for treating patients suffering from Chronic Fatigue Syndrome (CFS) with antigen-specific transfer factor (TF), which is active against EBV, HHV-6 and CMV, and that Wilson et al. disclose a method for producing an antigen-specific excreted transfer factor (TF) isolated from colostrum or milk of a bovine.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended the claims. Applicants note that the composition discussed in Ablashi et al. is active against both EBV and HHV6, and for CMV. Nothing in Wilson et al., when taken

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in combination with Ablashi et al., teaches removing the EBV and CMV transfer factor elements disclosed to somehow arrive at the claimed invention, especially in light of the fact that Abalshi et al. in combination with Wilson et al. suggest that both EBV and HHV6 need be controlled in treating CFS. Accordingly, the cited prior art references, even if combined as suggested by the Examiner, do not teach or suggest all the elements of applicants' claimed invention. Thus, applicants maintain that the claimed invention is not obvious in light of the prior art, and applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections under 35 U.S.C. §102(b)

The Examiner rejected claims 32-40, 42, 43, 46 and 47 under 35 U.S.C. §102(b) as allegedly anticipated by an advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p. 29, ("the 1998 advertisement"), in view of an advertisement by Chisolm Biological Laboratory in Positive Health News, Fall 1997, p. 27, ("the 1997 advertisement").

In response, applicants respectfully traverse the Examiner's rejection.

Claim 32 teaches a fluid consisting of a colostrum of a human herpesvirus-6A-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat, and claim 33 teaches a fluid consisting of a colostrum of a human herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat. The remaining rejected claims relate to claims 32 and 33.

Initially, applicants note that the 1998 advertisement does not teach the elements recited in the rejected claims, i.e. "a fluid consisting of a colostrum of a human herpesvirus-6A-immunized lactating bovid, wherein the colostrum has removed from it cells,

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casein and fat" or of a "a fluid consisting of a colostrum of a human herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat" as recited in claims 32 and 33, respectively, upon which claims 36-39 depend. In addition, the 1998 advertisement does not teach a method of treating chronic fatigue syndrome by administering such a fluid from a "human herpesvirus-6A-immunized lactating bovid" and of a "herpesvirus-6B-immunized lactating bovid" as recited in claim 40, upon which claims 42 and 43 depend, and as recited in claims 46 and 47. Accordingly, because all the elements of the rejected claims are not taught in the prior art reference, the rejection is improper, and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

In addition, applicants note that according to MPEP §2121, a prior art reference is assumed to be enabling if it "expressly anticipates or makes obvious all of the elements of the claimed invention".

Applicants note that the 1998 advertisement, in view of the 1997 advertisement, does not anticipate the claimed invention in that it does not teach either expressly or inherently a "fluid" consisting of a "colostrum of a human herpesvirus-6A-immunized lactating bovid" or of a "colostrum of a human herpesvirus-6B-immunized lactating bovid" from which the "cells, casein and fat" have been removed. Applicants further note that no lesser standard of enablement is applied to advertisements as compared to other types of prior art. See, e.g., M.P.E.P. §2121 stating that "the level of disclosure required within a reference to make it an 'enabling disclosure' is the same no matter what type of prior art is at issue."

In support of applicants' position that the references cited by the Examiner under 35 U.S.C. §102(b) are not enabling disclosures, applicants attach hereto as **Exhibit 1** a Declaration of co-inventor Gregory B. Wilson Under 37 C.F.R. §1.132. The

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attached Declaration states the following:

1. It is Dr. Wilson's opinion that, as of the priority date, based on the 1998 advertisement in view of the 1997 advertisement, and absent undue experimentation, one skilled in the art could not have made a fluid consisting of a colostrum of a human herpesvirus-6A-immunized lactating bovid or of a herpesvirus-6B-immunized lactating bovid, wherein the colostrum has removed from it cells, casein and fat. Dr. Wilson's opinion is based on the following points.
2. With regard to the Examiner's assertion that the 1998 advertisement teaches a product which (a) comprises an "antigen-specific transfer factor (TF) with an immunological stimulatory function" and (b) is "specific against particular antigen(s), including HHV6", Dr. Wilson notes that the advertisement does not teach this product to be a colostrum product, wherein colostrum is derived from an immunized lactating bovid and has removed from it cells, casein and fat.
3. With regard to the Examiner's assertion that the 1997 advertisement teaches the "Immunfactor [of Chisolm] is a colostrums product", Dr. Wilson notes that the 1997 advertisement (i) states that one should "not be fooled by simple dried colostrums/whey products (already marketed for years) which elicit a nonspecific immune response", yet (ii) does not indicate the source of the products offered in the 1997 advertisement.
4. It is also Dr. Wilson's opinion that when taken in view of the 1997 advertisement, the 1998 advertisement, as of the priority date, would not have taught one skilled in the art, inter alia, the steps of immunizing a bovid with human herpesvirus 6A or 6B, collecting the resulting

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colostrum of the lactating bovid, and removing cells, casein and fat, leading to the claimed fluids and related compositions and methods.

5. In summary, it is Dr. Wilson's opinion that as of the priority date, one skilled in the art would not have been able to make the claimed fluids and related compositions or practice the related methods based on the 1998 advertisement in view of the 1997 advertisement.

Applicants further note that M.P.E.P. §2121.02(I) states that "[i]t is possible to make a 35 U.S.C. §102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e. how to make or use the article disclosed. *If the reference teaches every claimed element of the article, secondary evidence, such as other patents or publications, can be cited to show public possession of the method of making and/or using*" (emphasis added). In regard to this, applicants contend that the secondary reference (i.e. the 1997 advertisement) cited by the Examiner to allegedly show the article of the 1998 advertisement is a colostrum/whey product is being improperly cited because the 1998 advertisement does not teach every claimed element of the article, as required by M.P.E.P. §2121.02(I). At the very least, the 1998 advertisement does not teach a "fluid" consisting of a "colostrum of a human herpesvirus-6A immunized lactating bovid" or of a "colostrum of a human herpesvirus-6B immunized lactating bovid", "wherein the colostrum has removed from it cells, casein and fat."

Applicants respectfully request that the Examiner consider the enclosed Declaration, and further request that the Examiner withdraw the rejection because the art cited under 35 U.S.C. §102(b) is not enabling.

Accordingly, in light of the arguments and amendments set forth herein, the 35 U.S.C. §102(b) rejection is improper and should be

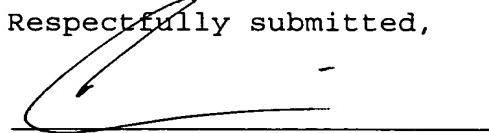
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withdrawn.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, apart from the enclosed \$1475.00 fee, including a \$1080.00 fee for a five month extension of time and a \$395.00 RCE fee, is deemed necessary in connection with the filing of this Amendment. If any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

2/17/06
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